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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/500,213	02/08/2000	Mark G. Schrom	16724-108	2262

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EXAMINER

EVANISKO, GEORGE ROBERT

ART UNIT	PAPER NUMBER
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3762

DATE MAILED: 09/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/500,213

Applicant(s)

SCHROM ET AL.

Examiner

George R Evanisko

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 July 2004.
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 43-56 and 62-78 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 43-56 and 62-78 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____

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DETAILED ACTION***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/23/04 has been entered.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 43, 44, 52, 53, 62, 63, 67, 68, 69, 71, 72, 73, 75, 76, 77, and 78 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cobian et al (5796044) in view of Iwaszkiewicz et al (4590950).

Cobian discloses the claimed invention having first and second (and third and fourth) conductors equally spaced from the longitudinal axis and connected to two ring electrodes (figures 8 and 9) except for how the conductors are connected to each ring electrode comprising first and second openings in the lead wall and a first and second conductive link in the first and second openings connecting the first ring electrode to the first and second conductor (and for the second ring electrode having third and fourth openings connected with third and fourth conductive links connected to the second ring electrode and second conductor). Iwaszkiewicz teaches that it is known to use first and second openings with first and second platinum conductive links connecting a ring electrode to a conductor to provide a redundant connection for connecting the ring electrode to the conductor and to provide an easily manufactured, flexible lead. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the medical lead as taught by Cobian, with first and second openings in the lead wall and a first and second platinum conductive link in the first and second openings connecting each ring electrode to each conductor as taught by Iwaszkiewicz, since such a modification would provide a medical lead using first and second openings having first and second platinum conductive links in the openings connecting each ring electrode to each conductor to provide a redundant connection for connecting the ring electrode to the conductor and to provide an easily manufactured, flexible lead.

In addition, the recitations of “electroplated”, “electroplating material” or “electroplating process” in the claims are more like method steps directed to how the links are produced rather than structural limitations and Iwaszkiewicz’s links, 20, are structurally equivalent to the claimed links (for claims 73 and 77, see the alternative 103 rejection below).

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For claims 73 and 77, in the alternative, Cobian in view of Iwaszkiewicz discloses the claimed invention except for the conductive links being electroplating material. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the conductive links in the medical lead as taught by Cobian in view of Iwaszkiewicz, with electroplating material as the conductive links since it was known in the art that medical leads use electroplating material as conductive links to provide a lightweight, flexible material that is easily produced to make a conductive link for electrical connection between elements.

Claim 43, 44, 52, 53, 62, 63, 67, 68, 69, 71, 72, 73, 75, 76, 77 and 78 are rejected under 35 U.S.C. 103(a) as being unpatentable over Iwaszkiewicz. The recitations of "electroplated", "electroplating material" or "electroplating process" in the claims are more like method steps directed to how the links are produced rather than structural limitations and Iwaszkiewicz's links, 20, are structurally equivalent to the claimed links (for claims 73 and 77, see the alternative 103 rejection below). In addition, Iwaszkiewicz shows the use of conductor 19 extending substantially the length of the body member and connecting to electrode 11 through two links, 20.

Iwaszkiewicz discloses the claimed invention except for the duplication and connection of the conductors (second), tunnels/openings/removals (third and fourth tunnels/openings/removals connected to the second conductor), links (third and fourth links in third and fourth tunnels/openings/removals), and electrode (second electrode connected to third and fourth link) to provide a second band distal electrode positioned proximate the outer surface of the body member. It would have been obvious to one having ordinary skill in the art at the time the

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invention was made to modify the medical lead as taught by Iwaszkiewicz, with a second duplicate connection of conductors, tunnels, links, and electrode to provide a second band distal electrode positioned proximate the outer surface of the body member since it was known in the art that medical leads use more than one electrode to easily provide stimulation/therapy to different and close locations in the body of a patient at the same time with only one lead. In addition, it has been held that duplication of parts is obvious to one having ordinary skill in the art at the time the invention was made (In re Harza, 124 USPQ 378).

In addition, Iwaszkiewicz discloses the claimed invention except for the first, second, third, and fourth conductors spiraled along substantially the length of the body member about the same distance from a longitudinal axis of the body member. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the lead with a second electrode as taught by Iwaszkiewicz in view of one having ordinary skill in the art, with first, second, third, and fourth conductors spiraled along substantially the length of the body member about the same distance from a longitudinal axis of the body member since it was known in the art that medical leads providing a second electrode using first, second, third, and fourth conductors spiraled along substantially the length of the body member about the same distance from a longitudinal axis of the body member to provide a second duplicate electrode on the distal end of the lead body to provide additional therapy to the body with the same lead and use multiple conductors spiraled about the same distance from a longitudinal axis of the body member to provide a lumen for insertion of additional elements and/or provides additional rigidity/flexibility to assist in insertion and adaptation of the lead and/or to provide a smaller lead and/or to provide a redundant connection to the electrode in case one of the conductors breaks.

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For claims 73 and 77, in the alternative, Iwaszkiewicz discloses the claimed invention except for the conductive links being electroplating material. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the conductive links in the medical lead as taught by Iwaszkiewicz, with electroplating material as the conductive links since it was known in the art that medical leads use electroplating material as conductive links to provide a lightweight, flexible material that is easily produced to make a conductive link for electrical connection between elements.

Claims 54, 66, and 70 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Iwaszkiewicz. Iwaszkiewicz has the width of the electrode, 11, as 0.3 mm (2.3 mm OD - 2.0 mm ID) and therefore is a thin film electrode. In addition, the first and second segments of the electrode are the proximal and distal segments of the electrode. Also, the conductors are shown spiraled at an angle of about 80 degrees (claims 66 and 70, for claim 70, the 103 rejection above provides the conductors being located the same distance from the longitudinal axis).

In the alternative, Iwaszkiewicz's discloses the claimed invention except for the thin film electrode and conductors spiraled at about 10 to about 80 degrees. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the medical lead as taught by Iwaszkiewicz, with the thin film electrode and conductors spiraled at about 10 to about 80 degrees since it was known in the art that medical leads use thin film electrodes to provide a small, flexible lead that is easily inserted into the body and since it was known that

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medical leads use conductors spiraled from about 10 to about 80 degrees to provide greater or lesser torque and flexibility to the leads.

Claims 45-50 and 56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Iwaszkiewicz et al. For claims 48, 49, 50, Iwaszkiewicz discloses a thin film electrode with the conductor being stainless steel or MP35N and spiraled at an angle of about 80 degrees. In the alternative, see the 103 rejection given in the preceding paragraph.

Iwaszkiewicz discloses the claimed invention except for the first conductor being embedded in the annular wall (claims 45 and 56), the outer diameter of the lead being about 2 French and internal diameter being 0.012 inch (claim 46), and the conductors having a substantially rectangular cross section, 0.004 inch wide by 0.002 inch high (claim 47). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the lead as taught Iwaszkiewicz, with the conductor being embedded in the annular wall, an outer diameter of the lead being about 2 French and internal diameter being 0.012 inch, and the conductors having a substantially rectangular cross section, 0.004 inch wide by 0.002 inch high, since it was known in the art that leads have conductors embedded in the annular wall to ensure stability of the conductors and overall strength of the lead; an outer diameter of the lead being about 2 French and internal diameter being 0.012 inch to allow the lead to be unobtrusively placed in small areas of the body and to prevent tissue damage and irritation; and the conductors having a substantially rectangular cross section, 0.004 inch wide by 0.002 inch high to provide a small diameter lead with flexibility in particular directions.

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In addition, it would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the lead as taught by Iwaszkiewicz with the outer diameter being about 2 French and internal diameter being 0.012 inch and the conductors having a substantially rectangular cross section, 0.004 inch wide by 0.002 inch high, because Applicant has not disclosed that the outer diameter being about 2 French and internal diameter being 0.012 inch and the conductors having a substantially rectangular cross section, 0.004 inch wide by 0.002 inch high, provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the thin electrode lead having circular conductors in a helical pitch as taught by Iwaszkiewicz because it will provide a small body implantable flexible lead that is easily and quickly produced.

Therefore, it would have been an obvious matter of design choice to modify Iwaszkiewicz to obtain the invention as specified in the claim(s).

Claims 51, 64, 74, and 77 are rejected under 35 U.S.C. 103(a) as being unpatentable over Iwaszkiewicz in view of Willis, 5433742 (or Gotthardt et al, 5016646).

Iwaszkiewicz discloses the claimed invention except for the conductive links being a conductive epoxy. Willis (or Gotthardt) teaches that it is known to use a conductive epoxy to provide a good mechanical and electrical connection between the conductors and electrode. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the medical lead as taught by Iwaszkiewicz, with the conductive links being a conductive epoxy as taught by Willis (or Gotthardt), since such a modification would provide a

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medical lead with conductive links being a conductive epoxy to provide a good mechanical and electrical connection between the conductor and electrode.

Claim 55 is rejected under 35 U.S.C. 103(a) as being unpatentable over Iwaszkiewicz.

Iwaszkiewicz discloses a thin film electrode. In the alternative, see the 103 rejection above.

Iwaszkiewicz discloses the claimed invention but does not disclose expressly the thin film electrode comprising a first layer of titanium, chromium, etc of 5 microns and a second layer of gold, platinum, etc of about 500 angstroms to about 50 microns. It would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the medical lead as taught by Iwaszkiewicz, with the thin film electrode comprising a first layer of titanium, chromium, etc of 5 microns and a second layer of gold, platinum, etc of about 500 angstroms to about 50 microns because Applicant has not disclosed that the thin film electrode comprising a first layer of titanium, chromium, etc of 5 microns and a second layer of gold, platinum, etc of about 500 angstroms to about 50 microns provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the thin electrode as taught by Iwaszkiewicz, because it provides a thin, small electrode that is easily inserted into the body.

Therefore, it would have been an obvious matter of design choice to modify Iwaszkiewicz to obtain the invention as specified in the claim(s).

Response to Arguments

Applicant's arguments filed 7/23/04 have been fully considered but they are not persuasive. The argument that the duplication of parts and/or obviousness rejection using the Iwaszkiewicz reference is not obvious with respect to the Applicants invention is not persuasive. The previously cited prior art reference of Dahl et al (4559951), the Winkler reference (5417208) recently cited in the IDS, and the cited Vaiani et al (5374285) reference and Peers-Trevarton reference (4437474) are four teachings of many that show the use of a duplicate electrode for a second distal band electrode to provide additional therapy to the body using only a single lead and show a first conductor and a second conductor being spiraled along substantially the entire body member at the same distance from a longitudinal axis of the body member (the references additionally show spiraling of the conductors at approximately 45-80 degrees). All four are teachings that show it is obvious to one having ordinary skill in the art to provide a duplicate electrode for a second electrode. The argument that including a second conductor in Iwaszkiewicz would not be allowed since the coil is virtually unitary (no spacings between the wire) is not persuasive since the prior art references show that a second conductor can be inserted between the coils of the first wire to provide a second electrode.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the

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applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to George R Evanisko whose telephone number is 703 308-2612. The examiner can normally be reached on M-F 6:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 703 308-5181. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


George R Evanisko
Primary Examiner
Art Unit 3762

9/17/04

GRE
September 17, 2004